IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OKLAHOMA

STATE OF OKLAHOMA, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Case No. 4:05-cv-00329-GKF-PJC**
	)	
TYSON FOODS, INC., *et al.*,	)	
	)	
Defendants.	)	
	)	

DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF DR. VALERIE J. HARWOOD PURSUANT TO *DAUBERT v. MERRELL PHARMACEUTICALS, INC.*

Defendants respectfully move the Court for an order excluding the testimony of Dr. Valerie J. Harwood as unreliable under Federal Rule of Evidence 702. *See Daubert v. Merrell Pharm., Inc*., 509 U.S. 579 (1993). Dr. Harwood purports to have identified—for the first time in history—a "poultry-specific biomarker," which she asserts can conclusively identify bacteria found in environmental samples as having derived from poultry litter. Dr. Harwood offered the same testimony during the preliminary injunction proceedings, but this Court concluded that her opinions were unreliable under *Daubert* because they were unpublished and had not been peer reviewed or tested by anyone outside of this litigation. Opinion & Order, Dkt. No. 1765 at 6-7 (Sep. 25, 2008). Nothing has happened subsequent to the Court's order to alter that conclusion: Dr. Harwood's testimony remains the same as it was at the prior hearing; the bases for her opinions are unchanged; Defendants have confirmed the weaknesses in her methodology; and in fact Dr. Harwood's work has been severely criticized and rejected by a leading journal to which it was submitted for peer review. The peer reviewers came observed the same flaws and came to the same conclusions as Defendants' experts and this Court, and pronounced Dr. Harwood's and Dr. Olsen's work on the alleged "poultry biomarker" to be in some respects "inappropriate" for publication in a scientific journal. *See* Ex. 1 at 1. At bottom, Dr. Harwood's biomarker theory and her conclusion that poultry litter poses a substantial threat to human health in the IRW is unreliable and would be confusing and unfairly prejudicial if presented to a lay jury. For these reasons, Dr. Harwood's testimony should be excluded under *Daubert*.

BACKGROUND

During the preliminary injunction hearing Dr. Harwood testified that she, "in conjunction with Northwind Inc. [had developed] a poultry litter biomarker … to use as a tracer for land applied poultry litter." Preliminary Injunction Transcript (herinafter "P.I.T.") 631:16-19 (attached at Ex. 2). They employed a process called polymerase chain reaction ("PCR"), which

uses chemical "primers" to replicate specific DNA sequences as "sort of a DNA Xeroxing machine." *Id.* at 654:23-655:1. She and her colleagues attempted to identify a DNA sequence, which, they asserted, was specific to poultry litter. This sequence, dubbed the "biomarker," is "a gene fragment [from a bacterium] that we were able to detect by PCR[, which] is highly associated with … contaminated chicken litter." *Id.* 646:20-24. They then developed new primers to specifically target this "biomarker" in environmental samples. *Id.* 649:3-658:1. Using these primers they then designed a "quantitative PCR assay" ("qPCR"), which, Dr. Harwood testified, allowed them to quantify the amount of "biomarker" present in a particular sample. *Id.* at 659:2-661:1. Dr. Harwood testified that using this assay she was able "to follow the pathway of … microbial contamination from poultry litter throughout the [IRW]." *Id.* 646:14-18, *see id*. 666:11-20.

Defendants moved to exclude Dr. Harwood's testimony as unreliable. *See* P.I.T. 652:25-653:17; Response to Plaintiffs' Bench Brief On Oral Motions To Exclude the Testimony of Valerie J. Harwood and Roger Olsen, Dkt. No. 1619 (Mar. 7, 2008). First, Defendants noted Plaintiffs' failure to perform any traditional fate-and-transport study to confirm Dr. Harwood's work. *Id.* at 2-4. Second, we explained how Dr. Harwood's method was novel, had been developed solely for litigation, and had never been published, peer reviewed, or otherwise independently tested. *Id.* at 10-17. Third, we argued that "were this theory subjected to rigorous independent review, impartial observers would identify a number of substantial and worrisome irregularities" including that the biomarker was not poultry-specific; that the sample sizes were not statistically significant; that Plaintiffs did not test most wildlife in the IRW to confirm the absence of the biomarker; that the biomarker did not correlate to indicator bacteria; and that the method did not control for alternative sources of indicator bacteria. *Id.* at 14-17.

The Court initially denied Defendants' motion to strike Dr. Harwood's testimony because

Daubert and its progeny allow judges sitting in a bench trial to fully hear disputed expert testimony and then determine its reliability. P.I.T. 653:11-15; Opinion & Order, Dkt. No. 1700 (May 5, 2008). However, after considering Dr. Harwood's testimony, the Court concluded that her testimony failed the standards for reliability set out in *Daubert*. Opinion & Order, Dkt. No. 1765 at 6-7 (Sep. 25, 2008). Specifically, the Court noted that her "work has not been peer reviewed or published" and that "the record … reveals no one outside this lawsuit who has either validated or sought to validate Harwood's … scientific work." *Id.* at 7.[1]

Dr. Harwood's expert report, *See* Ex. 3, served in May 2008, confirms that her testimony at trial will mirror the opinions she offered at the preliminary injunction hearing. Her report discusses bacteria-caused illnesses, *id.* at 3-8, water testing and public health, *id.* at 9-11, and water quality in the IRW, *id*. at 12-14. The focal point of her testimony, however, remains her "biomarker" theory—that she has developed a "method for detecting and quantifying fecal contamination from poultry litter [in] the IRW." *Id.* at 17. She reports that this "biomarker" is "specific" to poultry litter and has been "validated" by her own testing (not by external review). *Id.* at 17-20. She asserts that the biomarker correlates positively to fecal indicator bacteria in poultry litter, and that its presence in environmental samples "indicate[s] a substantial health threat to recreational water users due to the known association of pathogens such as campylobacter and salmonella with poultry feces." *Id.* She reports having identified this biomarker and indicator bacteria in environmental samples across the IRW, *id.* at 21-22, and concludes that "the disposal of poultry waste by land application in the IRW presents a substantial, serious, and immediate threat to human health," *id.* at 23.

[1] Plaintiffs appealed this ruling to the Tenth Circuit, arguing that by declining to exclude Dr. Harwood from the hearing, but then finding her testimony to be unreliable under *Daubert*, the Court committed a "legal impossibility." Appellant's Opening Brief at 45, *Oklahoma v. Tyson Foods*, No. 08-5154 (10th Cir. 2008). Oral argument was held on March 11, 2009.

Dr. Harwood has confirmed that her methodology is unchanged from the preliminary injunction hearing; while Plaintiffs have tested a handful of additional samples, her underlying methodology remains the same. Ex. 4 at 8:17-9:2, 99:5-18. Moreover, since testifying before this Court, she still has not performed any fate and transport analyses of bacteria in the IRW. *Id.* at 9:5-10:17. She still has neither cultured any bacterium that carries her biomarker, nor studied its fate and transport characteristics. *Id.* at 10:18-11:6. She still has not studied any additional sources of fecal indicator or pathogenic bacteria in the IRW apart from poultry litter. *Id.* at 13:8-14:5. In short, the biomarker theory she presents now is identical to the testimony the Court previously found to be unreliable under *Daubert*.

At the preliminary injunction hearing, Dr. Harwood testified that she intended to publish her findings in the *Journal of Applied and Environmental Microbiology* ("AEM"), but acknowledged that the manuscript had not yet "been subjected to peer review or scrutiny." P.I.T. 661:10-22. Subsequently, she, Dr. Roger Olsen, and Northwind scientists Dr. Tamzen Macbeth and Dr. Jennifer Weidhaas, submitted a manuscript to AEM. *See* Ex. 5. That article explained in detail the development of Dr. Harwood's work in this case, and then presented the results of some, but not all, of Plaintiffs' field testing. The manuscript concluded that while "the watershed is in fact being impacted by the application of poultry litter, … the magnitude of the impact … cannot be quantified with the limited number of environmental samples processed to date." *Id.* at 14.

The manuscript submitted to AEM deviated from Plaintiffs' work in this case in several important respects. First, its conclusions were much more ambiguous than those offered to this Court. While the authors equivocated that poultry litter's impact on the IRW "cannot be quantified," Dr. Harwood has and will testify that "the disposal of poultry waste by land application in the IRW presents a substantial, serious, and immediate threat to human health."

Compare Ex. 5 at 14, with Report at 23. Separately, the manuscript presented AEM with only a subset of Plaintiffs' testing data. The manuscript suggested that the authors had tested only 46 environmental samples, the results of which were nearly uniformly positive. In fact, Plaintiffs had tested more than 200 samples, with substantially less positive results. *See* Ex. 6. In order to ensure that AEM appreciated the context in which the manuscript was prepared and possessed all the information relevant to assessing its accuracy, Defendants wrote to AEM raising the same concerns that Defendants raised at the preliminary injunction hearing. *Id*.

On September 2, 2008, AEM rejected the manuscript. As AEM wrote to Dr. Harwood,

> [t]he [peer] reviewers expressed a number of concerns about the manuscript. These include questions regarding the specificity of the markers for chickens…, the lack of some controls…, and the lack of sufficient data to "validate" the markers for other applications…. In addition, it was felt that the presentation of the material was inadequate, and in some cases inappropriate, for a scientific journal. For these reasons, and the reasons in the attached reviews, I am unable to accept your manuscript for publication.

Ex. 1 at 1. The authors revised the manuscript and resubmitted it on December 4, 2008, for a second round of independent peer review.[2] AEM rejected the revised manuscript on January 23, 2009. As AEM wrote:

> Two of the reviewers expressed serious concerns regarding your manuscript, as detailed in their comments. One of the most serious concerns is the potential for application of the method to other geographic regions, as other studies have shown that these biomarkers lose specificity when tests are conducted using samples from a broader geographic field regardless of the assurance made that these primers may have a broader application. Other concerns are over the lack of necessary controls and the lack of appropriate statistical analyses to support your conclusions. For these reasons, and the reasons in the attached reviews, I am unable to accept your manuscript for publication.

[2] Plaintiffs did not disclose contemporaneously the September 2 rejection. Accordingly, on October 1, 2008, Defendants wrote to AEM again to pass along this Court's Order denying Plaintiffs' motion for a preliminary injunction, and again on December 8, 2008, to supply several of Defendants' experts' final reports. Defendants' correspondence with AEM was previously filed with the Court in its entirety as Exhibits H, J, and P to Defendant Tyson Food, Inc.'s Reply on Motion to Compel Production of Peer Review Materials, Dkt. No. 1897 (Feb. 27, 2009).

Ex. 7 at 1. Thus, Dr. Harwood's biomarker theory twice failed peer review and was twice rejected for publication "for scientific reasons." *Id.*

DISCUSSION

Federal Rule of Evidence 702 charges a district court to ensure that "all scientific testimony … is not only relevant, but reliable." *Daubert*, 509 U.S. at 589. In this case, the Court previously determined that Dr. Harwood's biomarker theory and associated conclusions were unreliable. Nothing has occurred subsequently to alter that conclusion, and Dr. Harwood's proposed opinions remain deficient under *Daubert* as both a matter of methodology and practice. Her "biomarker" method is novel and was generated solely for use in this litigation. Her methods are inconsistent with applicable standards, have not been validated by anyone not in Plaintiffs' employ, and the conclusions she would draw are not supported by the data. Finally, Dr. Harwood's proposed method has now been subject to and failed peer review. Her proposed testimony is unreliable and should be excluded under *Daubert*.

A. Dr. Harwood's Novel Methodology Was Devised Solely For This Litigation

The touchstone for *Daubert* reliability is whether the proposed expert testimony has some basis in science external to the lawsuit: "The adjective 'scientific' implies a grounding in the methods and procedures of science." *Id.* at 590. As the Tenth Circuit has observed, whether a theory was developed independent of litigation and has been subjected to peer review are "important *Daubert* considerations". *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886 (10th Cir. 2005). Conversely, scientific theories generated solely for the purpose of litigation are suspect: "[A] scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317-18 (9th Cir. 1995) (*Daubert II*). Indeed, hired expert testimony can "turn[] scientific analysis on its head[,] … reason[ing] from an end result in order to hypothesize what needed to be known but what was

not." *Mitchell v. Gencorp, Inc.*, 165 F.3d 778, 783 (10th Cir. 1999) (quotations omitted); *see also Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1420-21 (9th Cir. 1998); *Sorenson v. Shaklee Corp.*, 31 F.3d 638, 649 (8th Cir. 1994). Ultimately, "the examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine." *Perry v. United States*, 755 F.2d 888, 892 (11th Cir. 1985); *see Allgood v. GM Corp.*, 2006 WL 2669337, at **17-18 (S.D. Ind. Sept. 18, 2006) (rejecting as novel a source tracking methodology that employed a "ratio analysis" to establish a causal pathway).

Dr. Harwood's proposed methodology lacks any substantial scientific precursor external to this litigation. As she herself candidly admitted at the preliminary injunction hearing, "[t]here is no standard conventional method for specifically detecting poultry contamination in environmental waters." P.I.T. 648:13-17. Instead, she and her colleagues designed an entirely new methodology in an attempt to detect constituents derived from poultry litter. Ex. 3 at 17. This required them to isolate a previously unidentified bacterium, to extract from it a never-before-documented genetic strand, to demonstrate that it is not carried by other living creatures, and to design new chemical "primers" to allow a PCR process to reproduce that, and only that, specific strand. P.I.T. 646:14-658:10.

This methodology was novel in almost every respect. As Dr. Harwood's report acknowledges, when she began her work "[n]o published library-independent MST method was available in 2006 to specifically detect poultry fecal contamination." Ex. 3 at 17. Indeed, no scientist had previously identified any type of bacteria, let alone a specific strand of DNA, that is unique to poultry litter. Ex. 8 at 44:11-14. And certainly no one had ever designed or confirmed chemical primers to isolate it and it alone. Therefore, as one of Plaintiffs' consultants observed, "we would be justified in saying this stuff is not standard given that we're dealing with a potential biomarker that has not previously been demonstrated, and for which we had to design

new primers." Ex. 9. Or, as Dr. Macbeth observed, "[w]hile PCR itself may be standard, the process of developing the biomarker procedure is NOT standard…. The entire process is highly specialized and is more appropriately considered 'developmental' and 'cutting edge' rather than 'standard'." *Id.* (emphasis in original). Dr. Harwood, for her part, observed that "[t]his is method development in a relatively novel research area—nothing standard about it." *Id.*; *see* P.I.T. 713:9-716:12.

Dr. Harwood testified at the preliminary injunction hearing that her method is based on a reliable technique, namely PCR. P.I.T. 646:11-18; 713:9-14. But the novelty of her method is not simply the use of PCR. Rather, its novelty lies in the claim that these newly designed primers isolate and reproduce a strand of DNA (and reproduce only that strand) that is carried by a bacterium that is unique to poultry litter. *See* Ex. 8 at 259:7-262:15, 325:8-15. That representation is essential to Dr. Harwood's conclusion that the land application of poultry litter endangers public health, yet it is entirely unconfirmed by any prior (or subsequent) work.[3]

Plaintiffs' biomarker was thus developed expressly and solely for this litigation. Dr. Harwood did not begin her substantive work until the summer of 2005. P.I.T. 630:24-631:2. Northwind, for its part, was retained in the spring of 2005, Ex. 10 at 29:16-19, and did not finish developing the qPCR assay until late 2007, when it provided Dr. Harwood with the report that is the actual basis for her testimony, Ex. 8 at 225:11-17; Ex. 11. Dr. Harwood did not form her

[3] Indeed, the only specific prior work Dr. Harwood has ever referenced was an effort by Dr. Katharine Field of Oregon State University to isolate a marker for cattle. But, after years of testing and thousands of samples, Dr. Field was unable to identify a marker for anything more specific than ruminants generally. *See* Orin C. Shanks, *et al.*, *Basin-Wide Analysis of the Dynamics of Fecal Contamination and Fecal Source Pollution in Tilamoook Bay, Oregon*, 72 Jnl. of Applied & Enviro. Microbiology 5537 (2006); Anne E. Bernhard & Katherine G. Field, *A PCR Assay to Discriminate Human and Ruminant Feces on the Basis of Host Differences in Bacteroides-Prevotella Genes Encoding 16S RNA*, 66 Jnl. of Applied & Enviro. Microbiology 4571 (2000). The rigorous and sustained application Dr. Field undertook to support her limited claim of specificity is precisely what is missing from Plaintiffs' work.

conclusions in this case until late 2007, after receiving Northwind's report. P.I.T. 676:21-677:4. Yet long before then Plaintiffs' counsel determined what testimony Dr. Harwood would give. P.I.T. 674:22-676:18; Ex. 12 ("Dr. Jodi Harwood will testify that the types and volume of bacteria in the environment is likely from land applied poultry waste and viruses associated with it."). The biomarker research was undertaken solely to facilitate this anticipated testimony.

B. Dr. Harwood's Biomarker Methodology Is Methodologically Flawed, Unsupported by the Data, And Has Been Twice Rejected by Peer Review

The *Daubert* analysis explores both an expert's general methodology, as well as its specific application in the case at bar. As the Tenth Circuit has explained, "any step that renders the analysis unreliable renders the expert's testimony inadmissible[,] whether the step completely changes a reliable methodology or merely misapplies that methodology." *Mitchell*, 165 F.3d at 782 (quotations omitted; italics added). In applying *Daubert* the Court should examine a number of factors including:

> (1) whether the opinion has been subjected to testing or is susceptible of such testing; (2) whether the opinion has been subjected to publication and peer review; (3) whether the methodology used has standards controlling its use and known rate of error; (4) whether the theory has been accepted in the scientific community.

Truck Ins. Exch. v. MagneTek, Inc., 360 F.3d 1206, 1210 (2004). These factors assist the Court in assessing the degree to which an experts' opinion is founded on proper scientific methods. Peer review and publication in particular provide "a significant indication that [an expert's work] is taken seriously by other scientists." *Daubert II*, 43 F.3d at 1318 (9th Cir. 1995); *accord Truck Ins.*, 360 F.3d at 1210; *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1233 (10th Cir. 2004). While peer review does not guarantee validity, it will "increase the likelihood that substantive flaws in methodology will be detected." *Daubert*, 509 U.S. at 593. "Proposed testimony must be supported by appropriate validation" external from the proponent's own work. *Id.* at 590.

In considering a *Daubert* challenge a district court should both examine an expert's theory, and also assess the reliability of the expert's application of a particular methodology to the data and facts of the particular case at hand. An "expert['s] conclusions are not immune from scrutiny: 'A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.'" *Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1205-06 (10th Cir. 2002) (quoting *General Elec. Co. v. Joiner*, 522 U.S. 136, 147 (1997)). Specifically, the district court "'must assess the reasoning and methodology underlying the expert's opinion, then determine whether it is scientifically valid and applicable to a particular set of facts.'" *United States v. Benally*, 541 F.3d 990, 994 (10th Cir. 2008) (quoting *Burlington N. and Santa Fe Ry. Co. v. Grant*, 505 F.3d 1013,1030 (10th Cir. 2007)) (emphasis added); *see also Norris*, 397 F.3d at 885-86 (same); *Dodge v. Cotter*, 328 F.3d 1212, 1221 (10th Cir 2003) (same).

During the preliminary injunction process, Defendants challenged Dr. Harwood's reliability on several grounds. Each of these grounds has now been echoed by independent peer reviewers, including that Dr. Harwood's opinions have not been appropriately tested and validated, are inconsistent with applicable standards, and are susceptible to a substantial error rate. *Truck Ins.*, 360 F.3d at 1210. For the following reasons, Dr. Harwood's testimony should be rejected as unreliable under *Daubert*.

1. Dr. Harwood's Theory Is Not Substantiated By Any Traditional Fate and Transport Study

Plaintiffs' essential allegation is that bacteria and other constituents from poultry litter are moving from fields over substantial distances to contaminate recreational and ground waters in the IRW. Dr. Harwood's biomarker testimony attempts to provide a means of associating bacteria, metals, and nutrients in the environment with the land application of poultry litter. Ex. 4 at 151:16-20. Ordinarily, such a claim is supported by a traditional fate-and-transport study

designed to follow specific bacteria, chemicals, or metals of interest carefully through the environment. *See Hatco Corp. v. W.R. Grace & Co.-Conn.*, 836 F. Supp. 1049 (D.N.J. 1993) (discussing elements of fate and transport analysis). Not so in this case.

A proper study (if even possible in a million-acre watershed) would take into account the varied fate and transport characteristics of and differing correlations between different target constituents, including the many factors that slow or degrade alleged contaminants or bacteria including sunlight, oxygen, temperature, humidity, pH, salinity, desiccation, topography, vegetation, and predation. *Hatco*, 836 F. Supp. at 1060-61; P.I.T. 683:4-688:23; *see City of Wichita v. Trustees of APCO Oil Corp. Liquidating Trust*, 306 F. Supp. 2d 1040, 1109-10 (D. Kan. 2003) (rejecting as unreliable groundwater modeling developed in part by Roger Olsen because it failed to account for typical fate and transport considerations, instead proposing a novel and untested methodology devised for litigation); *Allgood, 2006 WL 2669337*, at **17-18 (rejecting novel "ratio analysis"). A proper study would also account and control for alternate sources of those constituents both at the alleged source and along the claimed fate-and-transport pathway. *Id.* at 1111-12 (excluding same for failure to account for alternate sources); *Kalamazoo River Study Group v. Eaton Corp.*, 258 F. Supp. 2d 736, 756-57 (W.D. Mich. 2003) (discussing need to consider alternate sources in fate and transport analysis).[4]

Plaintiffs have undertaken no such analysis. This was clear at the preliminary injunction hearing. *See, e.g.*, P.I.T. 680:16-18, 688:24-699:17 (Dr. Harwood did not conduct a fate and transport analysis); *id.* 301:21-302:10 (Dr. Teaf did not conduct a formal fate and transport analysis); *id.* 405:8-13 (Dr. Fisher did not conduct a fate and transport analysis of bacteria); Ex. 13 at 25:21-26; 318:21-319:6 (Dr. Olsen not asked to track movement of litter constituents from

[4] *See also Renaud v. Martin Marietta Corp.*, Inc., 972 F.2d 304, 307-08 (10th Cir. 1992) (fate and transport of chemical over an 11-year period not demonstrable from a single data point).

particular land-application sites to allegedly contaminated waters or sediments). Plaintiffs still have not done so. Ex. 4 at 9:9-13; Ex. 10 at 84:22-25, 86:21-87:2.[5] Dr. Harwood admits that for her biomarker to be an effective indicator of the presence of constituents derived from poultry litter, the biomarker and those constituents "would have to have certain fate and transport characteristics in common." Ex. 4 at 151:21-152:5. However, she still has not studied the fate and transport characteristics of her biomarker, of any specific bacterium, or other constituent of poultry litter in the IRW. *Id.* at 9:5-14:5.

2. Dr. Harwood's "Poultry-Specific Biomarker" Is Not Specific To Poultry

Dr. Harwood purports to have identified a method "for detecting and quantifying fecal contamination from poultry litter." Ex. 3 at 17. An important measure of reliability for such a method is the degree to which the "biomarker" is unique to a single type of host, and thus not widely present in other animals. Indeed, in Professor Harwood's own words, host specificity is the "holy grail" of microbial source tracking. P.I.T. 721:24-722:5. Yet, this allegedly "poultry-specific" biomarker is simply not specific to poultry.

Plaintiffs' own testing confirms that the biomarker is not "host-specific." Plaintiffs found the same genetic sequence in ducks and in geese, thus finding it in every bird species they tested. P.I.T. 722:24-723:6. Dr. Harwood's assertions of host-specificity are based on Northwind's work, which reported that the "biomarker has been shown to be specific to poultry litter." Ex. 11 at 11. But Dr. Macbeth, who led Northwind's research efforts, made clear that this claim is only "an accurate statement within the context of the samples that [Northwind] analyzed" in this litigation. Ex. 10 at 134:15-18.

This introduces substantial room for error. For example, Plaintiffs confirmed that their

[5] Dr. Olsen, remarkably, now disclaims any need even to account for fate and transport factors. Ex. 21 at 565:17-566:6.

primers would not replicate genetic sequences other than the biomarker by comparing the primers against the BLAST database of known microbial DNA sequences. Ex. 11 at 4-8. But the BLAST database is far from complete. Ex. 10 at 104:10-108:12. Indeed, as Dr. Myoda explains, fewer than 2 percent of all bacteria present in the environment have been cultured. Ex. 14 at 3. Therefore, as Dr. Macbeth candidly admitted, to the extent that a bacterium has not been sequenced and included in the BLAST database, she "cannot say whether or not the primers would reproduce it." Ex. 10 at 121:23-122:7; see *id.* at 114:9-20. She further agreed that the claim of host specificity is limited to only the handful of animals that Plaintiffs tested. *Id.* at 137:12-15 ("Q. When you say it's specific to poultry litter, you mean as compared to geese, ducks, cows, humans, and pigs? A. Yes."). Thus, when understood "in context," Plaintiffs' claim of host specificity is quite limited. Dr. Harwood simply does not know whether her DNA sequence is carried by 98 percent of the types of bacteria, or whether those bacteria are carried by the hundreds of species present in the IRW.

Dr. Harwood's claim of host specificity also relies on her assertion that a "melt curve" can distinguish between the biomarker sequence and any other DNA sequence that the primers do happen to reproduce. A "melt curve" is an assessment of how the two strands of a particular DNA splice disassociate when heated. Dr. Harwood represents in her report that a melt curve "is particular to a given DNA sequence." Ex. 3 at 20. But, as Dr. Macbeth agreed, a range of factors including the purity of the PCR product, varied salt concentrations, residual DNA or RNA present from the PCR process, or the presence of a DNA binding protein, can result in the same DNA sequence producing different melt curves. Ex. 10 at 147:21-153:19. In addition, Northwind added to its melt curve process a compound called "DMSO," which "helps stabilize double stranded DNA [to result in a] more uniform denaturing of the DNA sequence." *Id*. at 155:15-23. But different DMSO concentrations result in different melt-curve results, and

Northwind experimented with different concentrations to "optimize" their curve. *Id.* at 157:11-160:7; Ex. 14 at 31. These variables introduce a substantial potential error rate into Dr. Harwood's process and fundamentally undermine any claim to having demonstrated host specificity.[6] Despite the inherent uncertainty of this process, Dr. Harwood made no effort to quantify the extent of this unknown error rate.

This was not lost on AEM, which rejected Dr. Harwood's manuscript in part because the authors' claims of specificity were not substantiated. Ex. 1 at 1. One peer reviewer noted that "[t]he amplification of a goose and a duck sample with the 'litter-specific' primers suggests that *avian species in general may be detected*." *Id.* at 2 (emphasis added). The peer reviewer wondered further, "how can the authors conclude with confidence that a given water sample was not impacted by broiler chickens, layer chickens, migratory birds, or resident birds?" *Id.* Dr. Harwood's work thus failed peer review in part because her data and the asserted specificity of the primers was suspect. Ex. 7 at 2-3.

This skepticism was well placed in light of Dr. Myoda's findings. Dr. Myoda used Plaintiffs' primer set to test additional samples. Ex. 14 at 27. He isolated Plaintiffs' biomarker sequence from unused bedding material, *id.* at 27, goose flop, *id.* at 32, sand from a beach frequented by geese, *id.* at 32-33, other water fowl samples, *id.* at 33, and cow hide, *id.* at 33.

[6] These uncertainties manifested themselves in Northwind's work. Dr. Macbeth described Plaintiffs' melt peak results as "weird and [not] tight" and "messy and [not] consistent." Ex. 10 at 164:10-165:4; Ex. 15 at 1-2. Dr. Macbeth's colleague, Dr. Weidhaas, suggested leaving some melt curve results out of their final report because they "will be more 'ammunition' to the defense and any expert they hired should know to ask to see melt curves rather than us suggesting it to them." Ex. 10 at 168:2-13; Ex. 15 at 3. As Dr. Macbeth subsequently testified, "I think at the time [Dr. Weidhaas] was just thinking it was a bad thing if we were amplifying things that weren't specific to our marker." Ex. 10 at 168:16-19. Dr. Weidhaas ran this question past Dr. Harwood, who concurred in leaving them out. Ex. 15 at 6. But as Dr. Macbeth ultimately decided, "the melt peak analysis is an essential component of the overall data assessment and it absolutely should be reported." Ex. 10 at 169:22-25.

Plaintiffs' alleged "poultry-specific biomarker" appears to be anything but. *See also* Ex. 16 at 16-18 (Report of Dr. Herbert Dupont).

3. Dr. Harwood's Biomarker Process And Conclusions Are Inconsistent With Applicable Statistical Standards

Plaintiffs developed their primers from just two poultry litter samples. Ex. 11 at 1; Ex. 10 at 99:10-101:11. They then tested their primers on just 13 cattle, two swine, five duck, five goose, and six human composite fecal samples to determine whether any of these species carry the biomarker. Ex. 11 at 12-13. Based on these tests, Dr. Harwood testified that the biomarker has been "validated" as "strongly host associated." P.I.T. 723:4; Ex. 3 at 19-20. Dr. Harwood's conclusions, however, are not statistically supportable.

Plaintiffs' experts agree that accurately characterizing a broader population requires a statistically significant sample set. *E.g.* P.I.T. 737:23-738:2 (Dr. Harwood agrees that disease in a few animals does not categorize the breed); Ex. 10 at 102:10-18 (Dr. Macbeth agrees that in order "to develop an assay … that can be used to track … poultry litter anywhere in this watershed … it's important to start with a representative litter sample"). Yet, Plaintiffs' did not employ a statistician to evaluate their sample sets or conclusions. Ex. 8 at 70:18-71:1. Nor did either Northwind or Dr. Harwood perform any such analysis. Ex. 10 at 58:18-21, 127:9-14; Ex. 4 at 154:3-155:10. In fact, Dr. Harwood asserted that "[t]here are no calculations to do that." *Id.* at 110:2-7.

But as Defendants' expert statistician, Dr. Charles Cowan,[7] explains in his report, such calculations are readily possible and they demonstrate that Plaintiffs' tests prove neither the presence of the biomarker generally in poultry, nor the absence of the biomarker in any other

[7] Dr. Cowan is a former Chief Statistician for the FDIC, and a former Chief of the Survey Design Branch at the United States Census Bureau where he was responsible for evaluating the statistical issues associated with the decennial census. Ex. 17 at 1-2.

species. Ex. 17 at 52-60. Plaintiffs developed their biomarker from only two litter samples. Ex. 11 at 1; Ex. 10 at 99:10-102:18. Moreover, those two litter samples were "co-located," *i.e.* gathered from proximate locations, which increases the likelihood that they will be similar. *Id.* at 97:4-12. These samples say little regarding the broader population. Ex. 17 at 57 (Dr. Cowan explaining the shortcomings of "cluster sampling").

Plaintiffs claim to have then proved the absence of the biomarker from other animals by testing for it in 13 cattle, two swine, five duck, five goose, and six human composite fecal samples. Ex. 11 at 12-13. As Dr. Cowan explains, these sample sizes are too small to support Plaintiffs' claim of having "validated" the "specificity" of the biomarker to poultry alone. Only the cattle sample is large enough to draw any statistical conclusion, and even there the testing demonstrates only that the biomarker could be present in up to 60 percent of cattle inside and outside the IRW. Ex. 17 at 55-56. Plaintiffs' other sample sets were so small that no positive or negative inference is possible. *Id.* at 56.

Dr. Harwood notes in her report that Plaintiffs collected "composite" samples—samples that combine portions of numerous pats or scats. Ex. 3 at 19. This only further confounds Plaintiffs' results. On account of this sampling approach it is impossible to know how many animals were represented, or whether the samples represent a sufficiently wide and random geographic area as to accurately characterize the total population. Ex. 17 at 58-60. Moreover, there is no way to know whether a positive test for the biomarker resulted from a single or many animals. Ex. 14 at 24-25. At any rate, the fact that these "composite" samples were taken from the same field reduces, not enhances, their representativeness and utility. Ex. 17 at 57.

These shortcomings were again noted by AEM. As one peer reviewer concluded,

> the information presented as field validation was, in fact, a field application and provided little information to support the utility of the marker assay for field

> application. *The efforts described represent an uncontrolled trial from which no conclusions regarding the utility of the assay can be extracted.*

Ex. 1 at 2 (emphasis added). As another noted, "*the evidence presented in this paper does not indicate that use of the marker is sufficient to quantifiably track poultry fecal sources in environmental waters*, at least in the sense of 10% of E. coli or nutrients in this water body came from poultry-derived fecal contamination." Ex. 1 at 4-5 (emphasis added). One reviewer specifically noted the problem with using composite samples. "The authors … contend that their marker has a 100% specificity…. I am not convinced that their excellent specificity is not simply an artifact of using a composite sample." Ex. 7 at 2. Dr. Harwood's work was rejected by the peer reviewers in part as statistically unsupportable. "The authors claim to have developed a sensitive and specific marker for the identification of poultry litter as a source of bacterial contamination in runoff and surface water. However, the manuscript is lacking in controls and proper statistical analysis as to make this claim unsupportable." Ex. 7 at 2.

4. Dr. Harwood's Biomarker Was Developed Without Adequate Confirmation Of Its Absence From Other Species

The fourth flaw in Dr. Harwood's testimony was her failure to test any other animals for the presence/absence of the "biomarker." While Plaintiffs' limited tests of cows, pigs, ducks, geese, and humans say virtually nothing about its presence in those species, Plaintiffs made no efforts at all to test any of the other hundreds of species of animals and birds living in the IRW. This oversight again introduces substantial room for error into Dr. Harwood's testimony.

Dr. Clay's report details the abundance of wildlife inhabiting the IRW. Ex. 18. By canvassing the records of various governmental and non-governmental organizations, Dr. Clay documented over 130 different species of wild animals and birds in the IRW. *Id.* But apart from pigs, ducks, geese, cows, and humans, Plaintiffs tested not a single one. P.I.T. 726:6-727:4. Dr. Harwood explained to the Court that Plaintiffs selected the animals "that are most likely to

impact the watershed" and that "small birds" and others animals "aren't going to contribute a large microbial load to the water." *Id.* 727:6-17. This justification is suspect because Dr. Harwood is purporting to identify very small amounts of bacteria in the environment, and Plaintiffs never made any effort to determine the geographic spread of bacteria that are added to the environment of the IRW from other types of animals. *See, e.g., id*. 697:2-699:17. In drawing her conclusions, Dr. Harwood simply ignores that her biomarker bacteria was found in every bird species tested.

Ultimately, Plaintiffs' conclusion that the presence of the biomarker in an environmental sample indicates the presence of poultry litter constituents simply assumes the absence of the biomarker from animals apart from poultry. But subsequent work demonstrates that this assumption is false. Plaintiffs' own testing shows the biomarker present in ducks and geese. Dr. Harwood testified that she "suspect[s] that it's at a very low level in these animals and probably in very few animals." *Id.* 723:24-25. And Dr. Myoda's testing demonstrates its presence in a variety of sources. Ex. 14 at 34. Dr. Harwood never cultured the bacterium that carries the biomarker, and therefore did not study its fate and transport characteristics. Ex. 4 at 10:22-11:6. Dr. Myoda, on the other hand, did culture the bacterium, and his work demonstrates that Dr. Harwood's PCR target can persist for a long period of time. Ex. 14 at 23-24. Thus, if the biomarker is carried in a number of species of animals or birds, especially waterfowl, in the IRW, even in species with relatively small numbers, it would not be surprising to find the biomarker distributed in environmental samples.

The failure to account for other possible carriers undermines any claim that this marker has been "validated." As one AEM peer reviewer noted, "[t]he amplification of a goose and a duck sample with the 'litter-specific' primers suggests that *avian species in general may be detected*" by Dr. Harwood's test. Ex 1 at 1 (emphasis added). Another peer reviewer noted that

with regard to the biomarker, "'[v]alidated' is not an appropriate term attending to the performed study." Ex. 1 at 6. A third observed that the larger the area studied, the less likely it is that a biomarker will produce valid results. *See* Ex. 7 at 2-3. As the Court knows, the IRW covers more than a million acres.

The peer reviewers also criticized Dr. Harwood's failure to include sufficient control samples – samples of known unimpacted soils and waters – to document the absence of the biomarker from those sources. "[C]ontrol materials (samples) are missing in order to determine the feasibility of the approach to a real situation in the environment." Ex. 1 at 5. Another reviewer noted that on account of the lack of sufficient control samples the authors "do not present convincing data that the biomarker is not normally found in, at least some, soil and runoff without the presence of poultry litter." Ex. 7 at 2.

5. Dr. Harwood's Biomarker Does Not Correlate with Indicator Bacteria

Dr. Harwood claims that the biomarker indicates the presence of constituents derived from poultry litter. Ex. 4 at 151:16-20. She agrees that in order to do so effectively they "would have to have certain fate and transport characteristics in common" such that they move through the environment together. *Id.* at 151:21-152:5. Yet, she has not developed any meaningful correlations between the biomarker and any other constituent.

The only correlation presented in Dr. Harwood's report is between the biomarker and *E. coli* and *enterococci* in poultry litter. *See* Ex. 3 at 21. She reports that the biomarker correlated strongly to *enterococci* and positively with *E. coli*, and from this concludes that the presence of both in recreational waters indicates a substantial risk to human health from the use of poultry litter. *Id.* But this leaps from poultry litter to recreational waters while skipping a host of environmental influences in between. Dr. Harwood made no effort to show that the biomarker and indicator bacteria maintain this same correlation during land application, on field surfaces, in

runoff waters, in rivers and streams, in groundwater, in wells, or in springs, and certainly not in recreational waters. *See* Ex. 4 at 146:14-148:18. Nor did she study the fate and transport characteristics of the biomarker or any other bacterium in the IRW. *See id.* at 9:9-11:6. The analysis also ignores the fact that, as Dr. Harwood admits, the PCR assay cannot distinguish between live and dead bacteria, and can detect both. *See* Ex. 8 at 243:12-20. Given the abundant alternate sources for fecal indicator bacteria (discussed below) and potential alternate sources of the biomarker (discussed above) the assumption that this correlation is maintained and meaningful from growing house floor to recreational waters is unsustainable.

Moreover, as Dr. Myoda explains, even the correlation Dr. Harwood asserts in poultry litter is flawed as it is based on too few samples over too small a period of time to be meaningful. *See* Ex. 14 at 20-21. As Dr. Harwood admitted, if the biomarker and indicator bacteria respond differently to growing house conditions, that would frustrate any correlation between them. *See* Ex. 4 at 107:25-109:1. But Plaintiffs took too few tests to assess this potential confounding factor. *See* Ex. 14 at 21 (explaining that it is impossible to establish a temporal correlation based on data taken at a single point in time). Moreover, Dr. Harwood based her correlation on flawed and suspect data. First, the *enterococci* values for several of her samples were artificially truncated. *See* Ex. 14 at 21. Second, a meaningful correlation was achieved only by late addition of a highly suspect sample, which was initially recorded by Plaintiffs as "soil," not "litter." *Id.* at 21-23.

The failure to develop meaningful correlations was also noted by AEM's peer reviewers. One reviewer noted that the methods Plaintiffs used to enumerate fecal coliforms, *E. coli*, and *enterococci* are "very imprecise." Ex. 1 at 4. Another observed that the manuscript did not demonstrate a correlation between *E. coli* and the biomarker in poultry litter. Ex. 1 at 3. At the preliminary injunction hearing Dr. Harwood asserted that the biomarker correlates with indicator

bacteria in water. P.I.T. 669:20-672:16. She presented a similar correlation in her manuscript, which one peer reviewer addressed at length:

> In any given water sample, fecal contamination from any number of sources may be present. Thus, any validation for a relationship between poultry marker and fecal indicator must take into account the expected level of poultry contamination. Importantly, the ratio of marker to indicator would be relatively low for water with lesser poultry-origin contamination (bulk river water, especially upstream from poultry-amended fields), and relatively high with concentrated poultry contamination (as expected in runoff from litter-amended fields). *Lumping all water samples, without regard to the expected level of poultry-origin contamination, and looking for a direct correlation is not particularly informative and does not constitute validation*.

Ex. 3 at 6 (emphasis added). A later reviewer was more direct. "[T]he regression data presented in Figure 4 is meaningless. R2 is a guide to the 'goodness-of-fit' of the data to the regression line. It does not indicate whether there is an association between the variables that is statistically significant." Ex. 7 at 2. Dr. Harwood failed to demonstrate any sustained correlation.

6. Dr. Harwood Failed to Control for Alternate Sources of Bacteria

As explained above, Dr. Harwood assumes without demonstrating that the biomarker and indicator bacteria remain correlated from growing house to recreational waters such that the former indicates that the latter derived from poultry litter. But this assumption is confounded by the abundant alternate sources of indicator bacteria in the IRW.

Fecal indicator bacteria including fecal coliforms, *E. coli*, and *enterococci*, are shed by most living creatures in the IRW. P.I.T. 682:6-8; Myoda Rpt. at 14-15. Such bacteria can also persist in, and under some conditions even grow in, sediment and other environments. Ex. 16 at 8; Ex. 4 at 17:2-7. Therefore, as Dr. Harwood and Dr. Macbeth both grudgingly agreed at their depositions, poultry are not the sole source of fecal indicator bacteria in the IRW.[8] Ex. 4 at 155:11-156:5; Ex. 10 at 210:16-211:14. Yet, the correlations Dr. Harwood presented in her

[8] The pathogens to which Plaintiffs point, *salmonella* and *campylobacter*, similarly have many sources other than poultry. Ex. 16 at 14-15; Ex. 14 at 15-18.

paper and at the preliminary injunction hearing made no effort to control for alternate sources. Ex. 4 at 156:6-20. Without accounting for alternate sources of indicator bacteria it cannot be concluded, as Dr. Harwood does, Ex. 3 at 21, that its presence anywhere in the IRW indicates a health risk from poultry litter.

Plaintiffs' own experts recognized this flaw. After Dr. Harwood prepared her correlation for the preliminary injunction hearing, Plaintiffs' counsel provided it to Northwind for their review. Ex. 10 at 206:19-208:8. Dr. Weidhaas, trying to be encouraging, had this to say:

> Actually, I don't think this is all that bad. When the biomarker is quantifiable, the correlation with the coliforms is fairly good for environmental data. Also, there could be other sources of coliforms in the watershed that would contribute to the fecal material count, but that are not the poultry litter. *This is not good for the litigation against poultry farmers (i.e. other sources of fecal material)*, but it doesn't have any bearing on the validity of the biomarker.

Ex. 19 (emphasis added); *see* Ex. 10 at 208:9-212:24. As Dr. Weidhaas candidly inferred, the fact that fecal indicator bacteria come from every warm blooded creature in the IRW irretrievably confounds the conclusions Dr. Harwood attempts to draw. It is perhaps therefore not a surprise that Dr. Harwood's Report now simply skips this step. Ex. 3 at 19-21.

C. Dr. Harwood's Conclusions Regarding Risks To Human Health Are Unsupported by the Data, and Plaintiffs' Water-Testing Methods are Contrary to Established Scientific Methods

Dr. Harwood's ultimate conclusion is that the land application of poultry litter releases bacteria into the environment, which in turn pose a substantial risk to human health in the IRW. Ex. 3 at 3-14. This claim is not supported by the methods or data upon which Dr. Harwood relies, and is therefore unreliable.

Dr. Harwood opines that waterborne disease transmission is "common," that *campylobacter* and *salmonella* (the only pathogens for which Plaintiffs tested in this case) are commonly transmitted through water, and that exposure to waterborne pathogens most

commonly results in intestinal illness. Ex. 3 at 3; Ex. 4 at 40:8-19. With regard to recreational waters this is simply not the case. Dr. Harwood identified the CDC as the authoritative source for data on disease transmission. Ex. 4 at 39:17-40:4. The CDC reports that in the United States 80 percent of all campylobacter illness and 95 percent of all salmonella illness is foodborne, not waterborne. Ex. 16 at 15. Moreover, CDC identifies *cryptosporidium*, *giardia*, norovirus, *shigella*, and *E. coli O157:H7* as pathogens of concern in rivers and lakes, not *salmonella* and *campylobacter*. *See* Ex. 16 at 10; http://www.cdc.gov/healthywater/observances/rwipw.html (last visited May 8, 2009).[9] Moreover, Dr. Harwood's alleged heath risk depends on full body immersion, including immersion of the head. Ex. 3 at 3; Ex. 4 at 49:8-14. Yet, she has no idea how often various types of recreators become fully immersed in the IRW. She similarly alleges that certain groups such as infants, pregnant women, the elderly, and the immunocompromised are most at risk from waterborne pathogens, but again has no idea how often any of these categories of individuals experience full body immersion in the IRW. *Id.* at 55:22-56:19. Ultimately, Dr. Harwood agreed, most exposures to waterborne pathogens *do not* result in any illness at all. *Id.* at 49:22-50:17.

Nor has Dr. Harwood substantiated her claim that specific pathogens or conditions pose a threat in the IRW. Plaintiffs have not conducted any epidemiological work to assess illness rates in the IRW. *Id.* at 54:16-55:6. Dr. Harwood raises the specter of a number of diseases, but Plaintiffs have no evidence of any instances where these diseases resulted from exposure to the

[9] Food presents a more effective transmission media for bacteria than water because bacteria can readily grow on food products. Ex. 16 at 6-7. Food products legally sold in grocery stores commonly have much higher bacterial counts than were measured in the IRW. *Id.* Water, on the other hand, is ordinarily a hostile environment for bacteria. *Id.* at 10-11. The sort of bacteria than can cause waterborne illness by exposure in recreational waters are extremely low dose pathogens typically not associated with poultry litter, and for which Plaintiffs conducted no testing. *Id.* at 11-12. Indeed, the bacteria at issue in this case could cause waterborne disease only when present in such numbers as to be readily detectible. *Id.* at 11-13.

waters of the IRW. She is not familiar with any incidents of Acute Febrile Respiratory Illness in the IRW. Ex. 3 at 3; Ex. 4 at 52:10-18. Nor is she aware of any incidents of Reiter's Syndrome or Guillain-Barre Syndrome in the IRW caused by exposure to poultry litter. Ex. 3 at 6; Ex. 4 at 62:6-63:3. And, Plaintiffs never tested for pathogenic *E. coli* (which are in any case most commonly associated with cattle), and have no proof of their presence in IRW waters. P.I.T. 751:7-19; Ex. 16 at 11.

Plaintiffs, of course, did actually test for some pathogens in IRW waters but found little: Plaintiffs found low levels of salmonella; and essentially no campylobacter. Ex. 14 at 15-16. Dr. Harwood excuses this failure by claiming that the bacteria that Plaintiffs did not find *must* be present as "viable but not culturable," a state in which bacteria remain alive but do not respond to culture-based testing methods. Ex. 3 at 5. But as she now agrees, even assuming that such a state actually exists, *cf.* Ex. 14 at 16-18, such bacteria are readily detectible by non-culture based methods such as PCR. Ex. 4 at 57:4-6; Ex. 16 at 13-14; Ex. 14 at 17. Plaintiffs considered using such methods to test for pathogens. Ex. 4 at 37:3-13. Dr. Harwood testified specifically at her deposition in July 2008 that "we had some conversations about using PCR [but] we just never went any further with the PCR tests." Ex. 4 at 60:23-61:6. However, documents subsequently discovered from Northwind suggested that Dr. Harwood had in fact undertaken limited testing for Salmonella with a PCR method several months earlier in April 2008, but again found no pathogens and stopped conducting this testing. *See* Ex. 20 (handwritten note reading "Jody tested for Salmonella in 2 litter samples by PCR & did not find it").

Dr. Harwood also relied on a variety of flawed data. Importantly, Plaintiffs routinely failed to abide by the well-established rules governing how long surface waters may be held before being tested to enumerate bacteria in the sample. Ex. 14 at 10. Over *72 percent* of Plaintiffs' water samples failed to comply with the EPA-mandated 6-hour hold time for

enumerating bacteria in recreational water samples. *Id.* at 12-13. Accordingly, under EPA's standards, test results from these samples are unreliable and must be discarded. *Id.*

Plaintiffs' bacteria data are also not representative of conditions in the IRW. Plaintiffs' sampling was not random; bacteria levels were not calculated according to a 30-day geomean of five evenly spaced samples (as is standard for evaluating water quality); and sampling was biased towards high-flow (and therefore higher bacteria) measurements. Ex. 14 at 12.

Finally, Dr. Harwood's conclusion that poultry litter threatens human health in the IRW depends on her adherence to the indicator bacteria-based approach to water quality testing. Ex. 3 at 9-11. But, as Defendants presented at the preliminary injunction hearing, substantial doubt exists as to the reliability of this approach, especially with regards to recreational waters that are impacted by animal, not human, sources of bacteria. Ex. 14 at 3-8; Ex. 16 at 5-6. Indeed, one peer reviewer at AEM specifically noted this flaw in Dr. Harwood's work:

> Correlation of poultry markers with fecal indicators does not provide any evidence of human health risk. The relationship of fecal indicators with human health risk was developed at sites contaminated primarily with human waste (Dufour's publications, 1984 and 1986). *This relationship is not expected to be the same for water contaminated with feces from nonhuman sources.*

Ex. 1 at 3 (emphasis added).

In light of these methodological and data shortcomings, Dr. Harwood's conclusion that poultry litter poses a threat to human health in the IRW is not sufficiently grounded in accepted and reliable scientific practices as to be accepted by this Court.

CONCLUSION

For the foregoing reasons, Dr. Harwood's testimony should be excluded as unreliable under *Daubert*.

Respectfully submitted,

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I also hereby certify that I served the attached documents by United States Postal Service, proper postage paid, on the following who are not registered participants of the ECF System:

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___/s/ *Jay T. Jorgensen*_____